Publications reference number: PRN01663

Patient Group Direction (PGD) for the initial supply of ciprofloxacin to children under 12 years for post-exposure prophylaxis to tularemia

This PGD is for the initial supply of ciprofloxacin tablets or suspension to children under 12 years of age, exposed to a known or suspected deliberate release of tularemia, by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference:	Ciprofloxacin under 12 initial supply tularemia PGD
Version number:	5.0a
Valid from:	1 April 2025
Review date:	1 April 2027
Expiry date:	31 March 2028

The UK Health Security Agency (UKHSA) has developed this PGD for local authorisation

Those using this PGD must ensure it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)[1].

The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided.

As operation of this PGD is the responsibility of commissioners and service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD. Sections 2, 3 and 7 must be completed and amended within the designated editable fields provided, but only for the purposes for which these sections are provided, that is the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in Section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA Chemical, Biological, Radiological and Nuclear (CBRN) PGD templates for authorisation can be found from:
NHS England » Hazardous Materials (HAZMAT) and Chemical, Biological, Radiological and Nuclear (CBRN)

Any queries regarding the content of this PGD should be addressed to: SMA@ukhsa.gov.uk

[1] This includes any relevant amendments to legislation

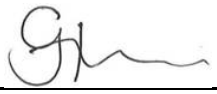
Change history

Version number	Change details	Date
PGD 2014/1	Original template developed and ratified	2 July 2014
PGD 2.0	1. Put into the new PHE template format 2. For use in anthrax only, tularemia put in separate PGD 3. Clinical indications: “another biological agent” removed 4. Abbreviated lists of warnings and contra-indications included- these medicines must be offered in all cases where exposure to these biological agents may have occurred unless there are life-threatening contra-indications. 5. Interactions: advice simplified. 6. References updated.	1 May 2016
PGD 3.0	1. Put into the new PHE template format 2. References updated	7 December 2018
PGD 4.0	1. Addition of ‘following deliberate release’ to page 1, clinical indication and criteria for inclusion for clarity 2. Removal of concurrent administration of aminophylline and theophylline from exclusion criteria 3. Cautions: amended wording for additional advice / actions to be taken; initiate supply for renal impairment to avoid delay; other medications added 4. Addition of 100mg tablets 5. Amended dose and frequency of administration section 6. Additional information under drug interactions section and patient advice section 7. Minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates	31 January 2022
PGD 5.0	1. Minor rewording, layout and formatting changes in line with UKHSA PGD templates 2. Title changed to include “prophylaxis” and clinical condition changed to specify exposure 3. Not showing symptoms added to inclusion criteria and information on cautions moved to cautions section 4. Previous severe reactions, history of tendon disease with quinolones, stages of renal impairment, additional drug interactions and no consent added to exclusion criteria 5. Wording under cautions changed, tendinitis risk, heart valve regurgitation and aortic aneurysm risk, diabetes, G6PD deficiency and medications requiring monitoring added with advice 6. Symptoms of tularemia added to advice if declines 7. If they are aged under 4 weeks of age, and history of allergic reaction and other exclusion criteria listed in actions to be taken if the individual is excluded, replaced with "If excluded for other reasons, refer to the supervising doctor or other prescriber for assessment”	27 January 2025

PGD 5.0 (continued)	8. Off-label use updated with information on crushing tablets 9. Age bands changed and associated dose changes under dose and frequency of administration 10. Additional information updated to remove “ciprofloxacin suspension is the preferred formulation for young children”, wording amended from “should be issued” to “is the preferred formulation for children” and age changed from 4 to 2 years and older, information on avoiding suspension for those with rare hereditary problems 11. Drug interactions updated to include specific information on interactions and medicines to avoid 12. Identification and management of adverse effects, advice to be given updated in line with MHRA alerts 13. MHRA leaflet added to written information to be provided 14. Advice/follow up treatment section for suspension updated to say to shake the bottle before administering, advice on crushing tablets and advice on ability to do skilled tasks	
PGD 5.0a	1. Wording amendments for consistency across PGDs 2. Wording in cautions amended for greater clarity 3. Drug interactions section refined to exclude rarely used or non-UK medicines	1 April 2025

1. PGD development

This PGD has been developed by the following on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Doctor (Expert panel chair)	Ruth Milton, Head of Advice, All Hazards Public Health Response, UKHSA		1 April 2025
Pharmacist (Lead Author)	Anna Wilkinson, Clinical Response Pharmacist, All Hazards Public Health Response, UKHSA		1 April 2025
Registered Nurse	Gemma Hudspeth, Senior Health Protection Practitioner, UKHSA		1 April 2025

This PGD has been peer reviewed by the CBRN PGD expert panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee

Expert panel

Name	Post
Claire Gordon	Consultant in Infectious Diseases and Deputy head of the UKHSA Rare and Imported Pathogens Laboratory
Diane Ashiru-Oredope	Lead Pharmacist, HCAI, Fungal, AMR, AMU and Sepsis Division, UKHSA
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Michelle Jones	Principal Medicines Optimisation Pharmacist NHS Bristol, North Somerset and South Gloucestershire ICB
Kiran Attridge	Senior Medical Advisor, All Hazards Public Health Response, UKHSA
Craig Prentice	Consultant Practitioner Paramedic, Surrey and Sussex Healthcare NHS Trust
Rachel Berry	Chief Pharmaceutical Officer's Clinical Fellow, HCAI, Fungal, AMR, AMU and Sepsis Division, UKHSA
Sherine Thomas	Consultant in Emerging Infections and Zoonoses, UKHSA
Sarah Upton	Lead Pharmacist for Medication Safety, community services, Locala Health and Wellbeing
Kelly Stoker	Nurse Consultant for Adult Social Care, Health Equity and Inclusion Health Division, UKHSA

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Insert authorising body name authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Limitations to authorisation
For instance any local limitations the authorising organisation feels they need to apply in-line with the way services are commissioned locally. This organisation does not authorise the use of this PGD by ….

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to insert contact details

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement, or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	To be completed by the organisation authorising the PGD. for example registered professionals with one of the following bodies: • nurses currently registered with the Nursing and Midwifery Council (NMC). • pharmacists currently registered with the General Pharmaceutical Council (GPhC). • paramedics currently registered with the Health and Care Professions Council (HCPC) • additional registered practitioners, appropriate for the role, who can legally operate under a PGD The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must have undertaken training appropriate to this PGD • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). • must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC) • must be competent to assess the individual and discuss treatment options • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy • authorising organisation to insert any additional requirements **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it**
Continued training requirements	Authorising organisation to Insert any continued training requirements

4. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	**Initial** chemoprophylaxis following exposure to a known or suspected deliberate release of tularemia For additional information on tularemia, including post-exposure prophylaxis, see CBRN guidance
Criteria for inclusion	Children aged from 4 weeks to less than 12 years of age following exposure to a known or suspected deliberate release of tularemia **And** Are not showing symptoms compatible with tularemia infection. Individuals with symptoms should be referred urgently to the supervising doctor. See Action to be taken if individual or carer declines prophylaxis section of this PGD and CBRN guidance for symptoms compatible with tularemia infection **Note:** The benefits of using ciprofloxacin to prevent the onset of disease outweigh the potential risks of using this medicine in children who should be given ciprofloxacin in the situation criteria set out above
Criteria for exclusion[2]	Individuals are excluded from this PGD if: 1. They are aged 12 years or over (see ciprofloxacin initial supply PGD for over 12s) 2. They are less than 4 weeks of age 3. They are known to be outside of weight range for age[3] 4. They have a known history of severe allergic reaction to ciprofloxacin, other quinolones or fluoroquinolones or to any of the listed excipients (see SPC) 5. They have had a known previous severe (life-threatening, disabling, incapacitating, or requiring hospitalisation) adverse reaction to a quinolone or fluoroquinolone antibiotic 6. They have a history of tendon disease/disorder related to ciprofloxacin or other quinolones or fluoroquinolones 7. They are taking interacting medicines as listed in the Drug interactions section of this PGD 8. They have known Chronic Kidney Disease (CKD) stages 4 or 5 (eGFR < 30ml/min/1.73m^2) or are on dialysis 9. Their parent or carer has not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005 has not been obtained) See Action to be taken if individual is excluded section of this PGD

[2] Exclusion under this Patient Group Direction does not necessarily mean the antibiotic is contraindicated, but it would be outside its remit and another form of authorisation will be required

[3] See British National Formulary for Children (BNFc)

Cautions including any relevant action to be taken (continued overleaf)	Although caution is advised for individuals with the following conditions or who are taking certain medicines, the benefit of taking ciprofloxacin to prevent tularemia outweighs the risk following a suspected or deliberate release of tularemia Provide the child's parent or carer with the advice outlined below Refer to the supervising doctor if concerned about an individual's risk for assessment and consideration of alternative antibiotics **1. At increased risk of tendinitis or tendon rupture:** • have renal impairment (those with CKD stage 4 or 5 or on dialysis are excluded from this PGD) • are taking corticosteroids • have a solid organ transplant Advise parents or carers to monitor for tendinitis (for example, painful swelling, inflammation). In young children who may not be able to report pain, be alert to lack of use of limbs or pain on movement. If signs of tendinitis occur, advise that the parent or carer stops giving ciprofloxacin and to seek immediate medical advice by dialling 111 or the child's GP for assessment **2. Conditions with risk factor for QT interval prolongation:** • cardiac disease (for example, heart failure, myocardial infarction, bradycardia) • congenital long QT syndrome • history of symptomatic arrhythmias • concomitant use of medicines known to prolong QT interval (for example, class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics) • electrolyte imbalance (for example, hypokalaemia, hypomagnesaemia) Advise parents or carers to monitor for the exacerbation or development of symptoms associated with QT interval prolongation. If symptoms develop, advise parents or carers to stop giving ciprofloxacin and to seek immediate medical advice for assessment and consideration of alternative antibiotics **3. History of, or at risk of, heart valve regurgitation or aortic aneurysm and dissection:** • a positive family history of aneurysm disease or congenital heart valve disease • pre-existing aortic aneurysm and/or aortic dissection or heart valve disease • presence of other risk factors or conditions predisposing for *both* aortic aneurysm and dissection and heart valve regurgitation/incompetence, such as: o connective tissue disorders such as Marfan's syndrome or Ehlers-Danlos syndrome o Turner syndrome o Behçet's disease o hypertension o rheumatoid arthritis • presence of other risk factors or conditions for aortic aneurysm and dissection, such as: o vascular disorders including Takayasu arteritis or giant cell arteritis o known atherosclerosis

Cautions including any relevant action to be taken (continued)	o Sjögren's syndrome • heart valve regurgitation / incompetence caused, for example, by infective endocarditis Advise parents or carers of the possibility of these rare events, and to seek urgent medical attention by dialling 999 if the child develops sudden-onset severe abdominal, chest or back pain Advise parents or carers to seek immediate medical attention by dialling 111 or via the GP if the child experiences a rapid onset of shortness of breath, especially when lying down flat in bed, swelling of the ankles, feet or abdomen or new-onset heart palpitations **4. Epilepsy or conditions that predispose to seizures and those taking medication that may predispose to seizures (for example NSAIDs):** Advise parents or carers to monitor for any increase in frequency or severity of seizures. If an increase in frequency or severity of seizures occurs, advise parents or carers to stop giving ciprofloxacin and seek urgent medical attention. Advise parents or carers to avoid giving a NSAID where possible (for example, ibuprofen) whilst taking ciprofloxacin **5. Diabetes (especially if receiving treatment with oral hypoglycaemic agents or with insulin):** Disturbances in blood glucose can occur. Advise parents or carers to carefully monitor blood glucose during treatment and to be alert to symptoms of hypoglycaemia and hyperglycaemia and to seek medical advice if required **6. G6PD deficiency:** There is a risk of haemolysis when ciprofloxacin is given to individuals with G6PD deficiency. If ciprofloxacin must be used, advise the parent or carer to monitor for signs of haemolysis. If signs of haemolysis develop, advise to stop giving ciprofloxacin and to seek urgent medical advice **7. Myasthenia gravis:** Advise parents or carers to monitor for any increase in severity of myasthenia gravis. If an increase in severity of disease occurs, advise that they seek urgent medical advice **8. Concomitant treatment with a vitamin K antagonist (for example, warfarin, phenindione and acenocoumarol):** Advise parents or carers to arrange for the child's INR to be monitored 3-5 days after starting treatment and to speak to their GP or anticoagulant clinic if they notice any signs of bleeding or unexplained/excessive bruising. **9. Concomitant treatment with methotrexate, aminophylline, theophylline, erlotinib, ruxolitinib, phenytoin, fosphenytoin, ciclosporin or clozapine:** Advise parents or carers to monitor for signs of toxicity, and to contact the service responsible for monitoring these medicines as soon as possible to inform them of the treatment and to arrange appropriate follow up and monitoring Refer to the SPC for ciprofloxacin for full details on special warnings and precautions for use

Action to be taken if the individual or carer declines prophylaxis	Refer the individual to the supervising doctor Advise the parent or carer of the possible consequences of declining prophylaxis and of alternative options Advise about the protective effects of the prophylaxis, risks of infection, and disease complications Advise to seek urgent medical attention if children develop symptoms compatible with tularemia or signs or symptoms of sepsis. Symptoms of pneumonic tularemia include: • fever, chills, headache, myalgia, sore throat, dry cough, pleuritic chest pain, dyspnoea See CBRN guidance for further information on symptoms to be aware of depending on the type of exposure Document the advice given and the decision reached
Action to be taken if the individual is excluded	Explain why they have been excluded If they are aged 12 years or over, refer to the Ciprofloxacin initial supply 500mg tablet PGD If excluded for other reasons, refer to the supervising doctor for assessment If they are 8 years and over, consider doxycycline (see doxycycline initial supply PGD) If the child is under weight for their age range, refer to the supervising doctor. If a different dose of ciprofloxacin for their age range is required, a Patient Specific Direction (PSD) will be needed. Document reasons for exclusion and any referrals that have been made
Arrangements for referral for medical advice	Follow local procedures for referral to the supervising doctor and/or other services

5. Description of Treatment

<table>
<tr><td>Name, strength and formulation of drug</td><td>Ciprofloxacin 100mg tablets, 250mg tablets, 500mg tablets, 250mg in 5ml suspension</td></tr>
<tr><td>Legal category</td><td>Prescription Only Medicine (POM)</td></tr>
<tr><td>Black triangle▼</td><td>No</td></tr>
<tr><td>Off-label use</td><td>Yes: ciprofloxacin is not licensed for use in tularemia. UK national guidance recommends its use

SPC dosing in children is based on weight. Age banding is recommended as per national guidance.

Manipulating solid dosage forms

In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available, provide advice on how to give doses by crushing tablets. Use in this way is outside the product licence and is thus off-label.

Ciprofloxacin tablets should ideally be swallowed whole, however they can be crushed and mixed with liquid or soft food if required.

The crushed tablet will taste very bitter, so it can be helpful to use a strongly flavoured drink (for example, blackcurrant cordial) or food (for example, jam or apple sauce) that the individual likes. Use a small amount of food or drink (for example, a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose. After mixing the crushed tablet, it should be given straight away

Where a product is recommended off-label consider, as part of the consent process, informing the individual/carer that the product is being offered in accordance with national guidance but that this is outside the product licence</td></tr>
<tr><td>Route / method of administration</td><td>Oral

Tablets to be swallowed whole with water, as this will help to prevent the formation of tiny crystals in the urine (crystalluria), and preferably on an empty stomach</td></tr>
<tr><td>Dose and frequency of administration

(continued overleaf)</td><td>Doses to be taken twice a day - see dosage table below.
<table>
<tr><th>Age</th><th>Dose (mg)</th><th>Dose (volume or quantity)</th></tr>
<tr><td>Less than 4 weeks of age</td><td colspan="2">Excluded</td></tr>
<tr><td>4 weeks to less than 8 weeks of age</td><td>50mg twice a day</td><td>1ml of 250mg in 5ml suspension twice a day</td></tr>
<tr><td>8 weeks to less than 6 months of age</td><td>75mg twice a day</td><td>1.5ml of 250mg in 5ml suspension twice a day</td></tr>
<tr><td>6 months to less than 1 year of age</td><td>100mg twice a day</td><td>2ml of 250mg in 5ml suspension twice a day</td></tr>
<tr><td>1 year to less than 2 years of age</td><td>150mg twice a day</td><td>3ml of 250mg in 5ml suspension twice a day</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>Dose and frequency of administration
(continued)</td><td>
<table>
<tr><td>2 years to less than 4 years of age</td><td>200mg twice a day</td><td>4ml of 250mg in 5ml suspension twice a day or
TWO 100mg tablets twice a day</td></tr>
<tr><td>4 years to less than 8 years of age</td><td>250mg twice a day</td><td>5ml of 250mg in 5ml suspension twice a day or
ONE 250mg tablet twice a day</td></tr>
<tr><td>8 years to less than 12 years of age</td><td>500mg twice a day</td><td>TWO 250mg tablets twice a day or
ONE 500mg tablet twice a day</td></tr>
</table>
</td></tr>
<tr><td>Duration of treatment</td><td>Ten (10) days</td></tr>
<tr><td>Quantity to be supplied</td><td>Suspension: 1 x 100ml suspension should be supplied per child irrespective of dose
A bottle of suspension must be discarded 14 days after reconstitution
100mg tablets: Children aged 2 years to less than 4 years of age: 40 tablets
250mg tablets: Children aged 4 years to less than 8 years: 20 tablets.
Children aged 8 years to less than 12 years: 40 tablets
500mg tablets: Children aged 8 years to less than 12 years: 20 tablets
When supplying under a PGD, this must be a complete manufacturer’s over-labelled original pack or over-labelled pre-packs. The individual’s name, the date and additional instructions must be written on the label at the time of supply. As split manufacturers packs cannot be supplied, if an over-supply is required, parents or carers must be advised to take any remaining medicine to a community pharmacy for destruction.</td></tr>
<tr><td>Additional information</td><td>Tablets (not suspension) are the preferred formulation for children aged 2 years and older unless they have medically confirmed swallowing difficulties
The suspension must be reconstituted according to the manufacturer’s instructions before handing to parent/carer or other responsible person
Supply an oral syringe with the suspension and instructions for using the syringe
The suspension should not be administered through a naso-gastric tube because of the risk of blocking the tube. Refer to the supervising doctor
The suspension should not be given to individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or saccharose-isomaltase deficiency. Refer to the supervising doctor
As the reconstituted suspension only lasts 14 days, any remaining solution should be taken to a community pharmacy for destruction</td></tr>
</table>

Storage	Store in original container below 25 ^{o}C Reconstituted suspension may either be stored at ambient temperatures up to 30 ^{o}C or it can be stored in a refrigerator
Disposal	Any unused product or waste material should be disposed of in accordance with local arrangements
Drug interactions	Concurrent medications should be checked for interactions. This list is not exhaustive. Full details of drug interactions are available in the SPC and the BNF. **Excluded from PGD** Where it is known an individual is concurrently taking one of the following medicines, ciprofloxacin should not be supplied under this PGD. Refer individuals to the supervising doctor. - agomelatine - domperidone - ergometrine, ergotamine or dihydroergotamine - fezolinetant - tizanidine The following medicines may require dose adjustments. Individuals should be referred to the supervising doctor: - guanfacine - tolvaptan - ropinirole - olanzapine - daridorexant - capivasertib - elacestrant - venetoclax - pirfenidone - eliglustat - zanubrutinib - pomalidomide - ibrutinib **Caution** Individuals who have **received live typhoid vaccine in the last 3 days, or live cholera vaccine in the last 10 days** should be advised to contact the clinic where the vaccine was administered or their GP for advice as ciprofloxacin may reduce the efficacy of these vaccines. Ciprofloxacin may increase the likelihood of side effects when taken with some medicines (for example, **anagrelide, chlorpromazine, duloxetine, melatonin, rasagiline, riluzole, roflumilast, sildenafil**). Advise parents or carers to be alert to any increase in adverse effects and to speak to the child's usual healthcare provider as soon as possible if adverse effects occur Individuals taking **zolmitriptan** should be advised that a maximum dose of 5mg of zolmitriptan should be taken in any 24-hours See Cautions section for advice for individuals taking medicines that prolong the QT interval, NSAIDs, vitamin K antagonists, corticosteroids, methotrexate, aminophylline, theophylline, phenytoin, fosphenytoin, ciclosporin, clozapine,erlotinib, or ruxolitinib Ciprofloxacin should be given 2 hours before, or 4 hours after **sevelamer, lanthanum, sucralfate, antacids** and any medicines or supplements containing **calcium, magnesium, aluminium**, **iron** or **zinc** that may reduce the absorption of ciprofloxacin

Identification and management of adverse reactions	Although there are potential and serious side effects, the benefit of using ciprofloxacin to prevent disease associated with tularemia exposure outweighs these risks Most commonly reported adverse reactions are nausea, diarrhoea and joint pain and joint inflammation in children. Nausea may be relieved by taking ciprofloxacin after food. Parents and carers should be alert to the possibility of joint pain and inflammation, and follow the advice outlined below Other side effects are classified as uncommon to very rare There have been cases of prolonged, disabling and potentially irreversible serious drug reactions reported rarely. Advise parents or carers to stop giving ciprofloxacin to their child immediately and seek urgent medical advice by dialling 999 if the following severe adverse effects occur: • anaphylaxis (delayed or immediate) • sudden, severe pain in the stomach, chest or back • seizures • thoughts about self-harm or ending their life Advise parents or carers to be alert to the possibility of the following rare effects, and to stop giving ciprofloxacin to their child immediately and seek urgent medical advice by calling their GP or 111 if the child experiences any of the following: • pain, swelling or inflammation of joints such as the shoulders, arms or legs or tendon pain or swelling. Very young children may not be able to report specific joint pain, so parents and carers should be alert to other signs such as lack of use of limbs or pain on movement • diarrhoea that lasts more than 4 days or contains blood or mucus • changes to vision, taste, smell or hearing • signs of liver disease (yellowing of the eyes or skin, unusually dark urine, itching or tenderness of the stomach) • symptoms of neuropathy (pain, burning, tingling, numbness or weakness in the legs or arms or difficulty walking) • sudden breathlessness, especially when lying down • new onset heart palpitations • swollen ankles, feet or stomach • changes in mood or behaviour, severe tiredness, anxiety, panic attacks, problems with memory or sleep (particularly for those individuals with a history of depression or psychosis) A detailed list of adverse reactions is available in the SPC
Reporting procedure of adverse reactions	All suspected adverse reactions in children should be reported using the Yellow Card system or search for MHRA Yellow Card in the Google Play or Apple App Store Any serious adverse reaction to the drug should be documented in the individual's record and the individual's GP informed

Written information to be given	Supply marketing authorisation holder's Patient Information Leaflet (PIL) An information leaflet explaining how to use and clean the oral syringe Consider providing the MHRA information leaflet on side effects
Advice /follow up treatment (continued overleaf)	Explain the treatment Advise the parent / carer the child should: • maintain adequate fluid intake • not take indigestion remedies sevelamer, lanthanum, sucralfate or medicines containing calcium, magnesium, aluminium, iron or zinc, 2 hours before or 4 hours after taking the medicine • not take with dairy products (for instance milk, yoghurt) or mineral-fortified fruit-juice (for instance calcium-fortified orange juice) • space the doses evenly throughout the day • keep taking the medicine until the course is finished, unless they are told to stop **For suspension**: Inform the parent/carer: • to shake the suspension bottle vigorously each time before use for approximately 15 seconds • although there may be suspension remaining after the initial ten day course, a further supply will be needed if a follow-on course is recommended • to take any remaining unused suspension to a community pharmacy for disposal **For tablets:** Inform the parent/carer: • these should be swallowed whole with water, as this will help to prevent the formation of tiny crystals in the urine (crystalluria), and preferably on an empty stomach • tablets should not be chewed • tablets can be crushed if necessary (see off-label section of this PGD) parents and carers should be advised that the tablets are very bitter in taste, and to encourage their children to swallow the tablets whole where possible • any unused tablets should be taken to a community pharmacy for disposal **Inform the parent / carer:** • for babies receiving milk feeds, to space the doses in the mid period between expected feed times • of possible side effects and their management • to read the PIL before giving the antibiotic and to seek medical advice if side effects, including painful or inflamed joints, or any other unexplained side effects on health are experienced • to seek immediate medical attention if the child develops signs or symptoms compatible with tularemia • the medicine can make the skin more sensitive to direct sunlight. Children should avoid exposure to excessive sunlight or use high SPF sunblock if prolonged exposure to the sun is unavoidable

Advice /follow up treatment (continued)	• the medicine may cause the child to feel tired or less alert. Children should take care when doing tasks that require coordination (for example, riding a bike) until they get used to the medicine • when the subsequent supply is due For individuals with conditions listed in the Cautions section, provide the additional recommended advice
Records	Record: • whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth, allergies, weight if known, and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of member of staff who supplied the product • name and brand of the product • date of supply • dose, form and route of administration of the product • quantity supplied • batch number and expiry date • advice given including advice given if the child is excluded or the parent/carer declines treatment • that the product was supplied via PGD All records should be signed and dated (or password-controlled on records) All records should be clear, legible and contemporaneous Contact details for the individual must be recorded. Local arrangements must ensure that contact is made between the designated centre and all individuals to discuss further supplies of ciprofloxacin or an alternative antibiotic, where appropriate. A computerised or manual record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	• Ciprofloxacin Summary of Product Characteristics accessed November 2024 • MHRA Fluoroquinolone Drug Safety Updates accessed 21 November 2024 • Chemical, biological, radiological and nuclear incidents: clinical management and health protection 2018 • British National Formulary for Children (BNFc) last updated 30 October 2024. Accessed November 2024 • NHS Medicines A-Z: Ciprofloxacin Accessed December 2024 • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions updated 27 March 2017 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions updated 27 March 2017 • Health Technical Memorandum 07-01: Safe and sustainable Management of Healthcare Waste. 7 March 2023

7. Practitioner authorisation sheet

Name PGD vXX.XX Valid from: XX/XX/20XX Expiry: XX/XX/20XX

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **insert name of organisation** for the above-named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.